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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	5

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/30/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 37-55 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-36 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 37-55 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39 and 53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 06/223,108. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the sequences in the claims are the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 06/223,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequences in the claims are the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 41 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 06/223,108. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the sequences in the claims are the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37, 38, and 42-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7, 43, and 44 of copending Application No. 06/223,108 in view of Claims 1-18 of U.S. Patent No. 4,530,901 (Weissmann). Claims 5-7, 43, and 44 of copending 06/223,108 disclose the same DNA sequences as are used in the instant claims. The Weissmann patent claims vectors, host cells, and the use of vectors and host cells that require the same gene expression control elements as are required in the instant claims. It would have been obvious for one of ordinary skill in the art to use the gene control elements and host cells in the claims of the Weissmann patent to express the DNA

sequences claimed in copending Serial No. 06/223,108 in order to make large amounts of human α-IFN.

This is a provisional obviousness-type double patenting rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 37, 42-44, 46, 47, and 49 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Nagata et al (Nature 284: 316 (1980)). The claims are embraced by the DNAs, vectors, and host cells of Nagata et al in that the claims also embrace DNAs that encode mature α-IFNs. Applicant cannot rely on foreign priority document EP 80300079.3 because the foreign priority document does not disclose the difference between mature α-IFN and pre α-IFN. The signal sequence for α-IFN is disclosed in Nagata et al at pages 319 and 320.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 305-3014. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.

JAMES MARTINELL, PH.D.
SENIOR LEVEL EXAMINER
GROUP 1800